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EXAMINER	
ROYDS, LESLIE A	
ART UNIT	**PAPER NUMBER**
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/774,697	COUCH ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-28 are presented for examination.

Applicant's Amendment filed March 1, 2007 has been received and entered into the present application.

Claims 1-28 remain pending and under examination. Claims 1 and 16 are amended.

Applicant's arguments, filed March 1, 2007, have been fully considered. Rejections and objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and objections are either reiterated or newly applied. They constitute the complete set of rejections and objections presently being applied to the instant application.

Objection to the Specification

Applicant traverses the maintenance of the objection to the specification for containing browser-executable code and/or a hyperlink, stating that, "Applicant deleted the internet address hyperlink by cross-out and added the internet address without the hyperlink. Additions to the specification must be shown by underlining the added text. 37 C.F.R. §1.121(b)(ii). It is this underline that was mistaken for a hyperlink by the Examiner, i.e., Applicant merely added the address back into the specification without the hyperlink." Please see page 6 of Applicant's remarks.

Applicant's traversal has been fully and carefully considered in its entirety, but fails to be persuasive.

Applicant's attention is directed to MPEP §608.01(VII), which states, "Examiners must review patent applications to make certain that hyperlinks and other forms of browser-executable code, especially commercial site URLs, are not included in a patent application. 37 CFR 1.57(d) states that an incorporation by reference by hyperlink or other form of browser executable code is not permitted. ***Examples of a hyperlink or a browser-executable code are a URL placed between these symbols "< >"***

and http:// followed by a URL address. When a patent application with embedded hyperlinks and/or other forms of browser-executable code issues as a patent (or is published as a patent application publication) and the patent document is placed on the USPTO web page, when the patent document is retrieved and viewed via a web browser, the URL is interpreted as a valid HTML code and it becomes a live web link. When a user clicks on the link with a mouse, the user will be transferred to another web page identified by the URL, if it exists, which could be a commercial web site. USPTO policy does not permit the USPTO to link to any commercial sites since the USPTO exercises no control over the organization, views or accuracy of the information contained on these outside sites. If hyperlinks and/or other forms of browser-executable code are embedded in the text of the patent application, examiners should object to the specification and indicate to applicants that the embedded hyperlinks and/or other forms of browser-executable code are impermissible and require deletion. This requirement does not apply to electronic documents listed on forms PTO-892 and PTO/SB/08 where the electronic document is identified by reference to a URL."

Accordingly, in view of such guidance, Applicant's replacement of the hyperlink with the web address in http:// format is still impermissible and requires deletion from the specification.

For these reasons, the objection to the specification remains proper and is **maintained**.

Claim Rejections - 35 USC § 112, Second Paragraph (New Grounds of Rejection)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Present claim 1 is directed to a pharmaceutical combination comprising an effective amount for a day of l- and d-amphetamines, each in base and/or salt form, and wherein the molar ratio of l-

amphetamine to d-amphetamine released from the pharmaceutical composition in a time period later in the day is higher than said ratio released therefrom in a time period earlier in the day.

In particular, there is insufficient antecedent basis for the limitation "the pharmaceutical composition" in present claim 1, since any reference to a "pharmaceutical *composition*" is noticeably absent in said claim.

For these reasons, the claims fail to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and are, thus, properly rejected.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11, 14-15 and 22-24 remain rejected under 35 U.S.C. 102(b) as being anticipated by Burnside et al. (U.S. Patent No. 6,322,819; 2001), already of record, for the reasons of record set forth at pages 5-7 of the previous Office Action October 20, 2006, of which said reasons are herein incorporated by reference.

Claims 1-15 and 27-28 remain rejected under 35 U.S.C. 102(b) as being anticipated by Patrick et al. ("Pharmacology of Methylphenidate, Amphetamine Enantiomers and Pemoline in Attention-Deficit Hyperactivity Disorder", 1997; p.527-546), already of record, for the reasons of record set forth at pages 7-8 of the previous Office Action October 20, 2006, of which said reasons are herein incorporated by reference.

Rejection of claim 16 over Patrick et al. is hereby **withdrawn** in view of Applicant's amendment.

Response to Applicant's Arguments

Applicant traverses the present rejection, stating that a release profile is not a function or use, as the Examiner contends, but a physical characteristic of the claimed pharmaceutical combination. Applicant further submits that even if the release ratio profile is labeled a functional limitation, the MPEP clearly states that functional limitations cannot be ignored. Applicant relies upon MPEP §2173.05(g) ("A functional limitation must be evaluated and considered, just like any other limitation of the claim...") and also *Hofer v. Microsoft Corp.*, 74 USPQ2d 1481 (Fed. Cir. 2005) ("[A] 'whereby' clause generally states the result of the patented process. However, when the 'whereby' clause states a condition that is material to patentability, it cannot be ignored in order to change the substance of the invention.") Applicant concludes that the cited references are not anticipatory because they do not disclose the claimed release ratio profile.

Applicant's traversal has been fully and carefully considered in its entirety, but fails to be persuasive.

First, Applicant's attention is directed to MPEP §2106[R-5](II)(C), which states, "The subject matter of a properly construed claim is defined by the terms that limit its scope. It is this subject matter that must be examined. As a general matter, the grammar and intended meaning of terms used in a claim will dictate whether the language limits the claim scope. Language that suggests or makes optional but does not require steps to be performed or does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation. The following are examples of language that may raise a question as to the limiting effect of the language in a claim: (A) statements of intended use or field of use, (B) "adapted to" or "adapted for" clauses, (C) "wherein" clauses, or (D) "whereby" clauses."

Applicant's claim 1 presents a "wherein" clause, not a "whereby" clause as alleged at page 8 of Applicant's remarks. The "wherein" clause has not been ignored, but rather has been analyzed to determine if it is of limiting significance in accordance with the guidance provided by the MPEP. As a

result, though the functional limitations have been evaluated and considered just like any other limitation of a claim, it remains that the instant "wherein" clause (i.e., see claim 1) does not provide a limiting effect upon the claimed composition because it does not require steps to be performed and clearly does not limit the claimed pharmaceutical combination to a particular structure. Rather, it characterizes the function and/or effect of the composition after administration. In view of such, and further in view of the fact that the presence of the word "released" is clearly indicative of a function of the composition that happens after administration, the instant "wherein" clause has no limiting effect upon the claim.

Furthermore, since the claim fails to set forth any physically or structurally limiting language other than the presence of a combination comprising l- and d-amphetamine, the claimed combination amounts to no more than a combination of both l-amphetamine and d-amphetamine. Accordingly, the prior art need only be as specific as the physical and structural components of the claim in order to properly anticipate. In the present case, because Burnside et al. and/or Patrick et al. explicitly teach pharmaceutical compositions of both l-amphetamine and d-amphetamine, the references properly anticipate the claimed composition.

Furthermore, it is noted that once a composition has been administered to a subject, the skilled artisan has no control over its effect on or its function in the host subject. In other words, whatever end-function or effect or, in the instant case, the ultimate release, attributable to the claimed combination of l-amphetamine or d-amphetamine that happens as a result of the administration of the composition does not ultimately limit the physical or structural characteristics of the claimed combination. Accordingly, the non-limiting nature of the "wherein" clause applies equally to the method claims that are directly dependent from and, thus, require the administration of, a combination according to claim 1.

Lastly, instant method claims 27-28 are directly dependent from instant claim 1 and are, thus, subject to the same claim interpretation as claim 1 set forth *supra*, i.e., that the "wherein" clause does not have a limiting effect on the claimed combination since it is a characterization of the function and/or

property(ies) of the composition *after* administration. Accordingly, since the cited references clearly teach combination products comprising both l- and d-amphetamine for the treatment of ADHD, the references properly anticipate the claims.

For these reasons, and those previously made of record at pages 5-8 of the Office Action dated October 20, 2006, rejection of claims 1-16, 22-24 and 27-28 under 35 U.S.C. 102(b) remains proper and is hereby **maintained**.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-28 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Patrick et al. ("Pharmacology of Methylphenidate, Amphetamine Enantiomers and Pemoline in Attention-Deficit Hyperactivity Disorder", 1997; p.527-546) in view of Epstein et al. (WO 2002/039998; 23 May 2002), Burnside et al. (U.S. Patent No. 6,322,819; 2001), STN Registry File (Registry No. 156-34-3) and Tulloch et al. ("SLI381 (Adderall XR), a Two-Component, Extended Release Formulation of Mixed

Amphetamine Salts: Bioavailability of Three Test Formulations and Comparison of Fasted, Fed and Sprinkled Administration, *Pharmacotherapy*, 2002; 22(11):1405-1415), each already of record, for the reasons of record set forth at pages 9-13 of the previous Office Action dated October 20, 2006, of which said reasons are herein incorporated by reference.

Applicant traverses the instant rejection, stating that the rejection fails to set forth a *prima facie* case of obviousness. Applicant submits that none of the cited prior art, alone or in combination, discloses or suggests increasing the release ratio of l- to d-amphetamine as the day progresses. Applicant additionally alleges that the art does not provide motivation to the skilled artisan to vary the l- to d-release ratio as the day progresses in the claimed manner.

Applicant's traversal has been fully and carefully considered in its entirety, but fails to be persuasive.

In response thereto, Applicant's attention is directed above to the discussion of the claimed pharmaceutical combination and the "wherein" clause contained therein, which, for the reasons set forth *supra*, does not have a limiting effect on the claim. Further, the method claims dependent from such a combination are also not limited by such a clause. Accordingly, the cited prior art clearly teaches the physical and structural requirements of the claimed pharmaceutical combinations of l- and d-amphetamine, each in base and/or salt form, for the treatment of ADHD and, thus, clearly sets forth a *prima facie* case of obviousness. Please reference the rejection under 35 U.S.C. 103(a) at pages 9-13 of the previous Office Action.

With regard to method claims 16-20, Applicant is reminded that the claims do not, in fact, specifically recite the limitation of "increasing the release ratio of l- to d-amphetamine as the day progresses" as Applicant asserts at pages 9-10 of the remarks. Rather, independent method claim 16 solely requires that the molar ratio of l-isomer to d-isomer administered per day is greater than 1:3. As provided for at pages 9-13 of the previous Office Action, one of ordinary skill in the art at the time of the

invention would have found it *prima facie* obvious, and would have been motivated, to use more l-isomer than d-isomer in a combination 1:3 l-/d-amphetamine product for the treatment of ADHD because the l-isomer has much greater efficacy in improving long-term memory and has also not been shown to be addictive, whereas the d-isomer has clearly been shown to be addictive, as taught by Epstein et al. Please see page 26, l.26-32 of Epstein et al. Accordingly, Applicant's argument that the cited references fail to show this release feature of Applicant's invention is not persuasive because this release feature upon which Applicant relies to demonstrate patentable distinction (i.e., increasing the release ratio of l- to d-amphetamine as the day progresses) is not recited in the rejected claim(s) (see, e.g., claim 16). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

It is acknowledged that present claim 20, in fact, does recite the administration of a greater amount of l-isomer than d-isomer in a later dose given to the patient in a day than the first dose, which contains more d-isomer than l-isomer. However, it is noted again that this limitation is not commensurate in scope with what Applicant continues to allege is the patentable distinction. For example, Applicant has failed to define when the later dose is administered, which, accordingly, means that a "later" dose is reasonably interpreted to be one that is given sequentially after the first dose, and not necessarily "later in the day" as Applicant asserts. In other words, Applicant is again arguing features that are not claimed.

Applicant additionally alleges a lack of motivation to vary the l- to d-release ratio as the day progresses in the claimed manner. However, as noted *supra*, the claims do not, in fact, recite this specific feature upon which Applicant relies to show patentable distinction. Furthermore, Applicant has not specifically raised any issues of material fact by addressing the discussion or motivation provided at pages 9-13 (specifically, page 12) of the previous Office Action as to why one of skill in the art would have been motivated to increase the amount of l-isomer or to administer more l-isomer than d-isomer in a later dose, but rather just alleges that motivation is not provided. In the absence of any discussion as to

why the prior art fails to provide motivation to do so, in view of the cited teachings and motivation provided, the rejection clearly provides motivation to modify the prior art in the manner that Applicant has claimed. Accordingly, the rejection appears to remain proper, absent factual evidence to the contrary.

For these reasons, and those previously made of record at pages 9-13 of the previous Office Action dated October 20, 2006, rejection of claims 1-28 remains proper and is **maintained**.

Double Patenting

Obviousness-Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-15 and 22-26

Claims 1-15 and 22-26 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the composition claims of U.S. Patent Nos. 6,605,300; 6,322,819; or 6,913,768, and are provisionally rejected over the composition claims of U.S. Patent Application Nos. 11/091,011; 10/758,417; or 11/030,174, each already of record, for the reasons of record set forth at pages 13-15 of the previous Office Action dated October 20, 2006, of which said reasons are herein incorporated by reference.

Provisional rejection of the present claims over U.S. Patent Application Nos. 10/443,151 or 11/150,311 have each been **withdrawn** in view of the fact that the '151 and the '311 applications are each abandoned and are, thus, no longer pending before the Office.

Applicant's request that the rejections be held in abeyance until allowable subject matter has been identified is noted.

In view of the fact that allowable subject matter has not been identified at the present time, and further in view of the fact that Applicant presents no arguments or Terminal Disclaimers regarding the obviousness-type double patenting rejections of record, the rejections remain proper for the reasons set forth at pages 13-15 of the previous Office Action and are, therefore, **maintained**.

Claims 16-21

Upon reconsideration of the rejections under the judicially created doctrine of obviousness-type double patenting in view of Applicant's amendments to the claims, the rejection(s) of claims 16-21 over the method claims of U.S. Patent Application Nos. 11/030,174 or 11/150,311 or the method claims of U.S. Patent No. 6,913,768 have each been hereby **withdrawn**.

Conclusion

Rejection of claims 1-28 remains proper and is **maintained**.

No claims of the present application are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-**

MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie A. Royds
Patent Examiner
Art Unit 1614

May 9, 2007

Ardin H. Marschel 5/12/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER